PATENT
Docket No.: 48317USA3M.032

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET AL. Group Art Unit:

Express Mail Label No.: EL 599 632 450 US

Filed: April 18, 2001 Examiner:

For: FILTERING FACE MASK THAT HAS A NEW EXHALATION VALVE

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Please amend this application as set forth below.

IN THE TITLE:

Please replace the present title with the following title: --FILTERING FACE MASK THAT HAS A NEW EXHALATION VALVE--.

IN THE SPECIFICATION:

Page 1, lines 8-10, delete the paragraph and insert the following:

This is a division of United States Patent Application Serial No. 08/240,877 filed May 11, 1994, which is a division of Application No. 07/981,244, filed November 25, 1992 (now U.S. Patent No. 5,325,892), which is a continuation-in-part of Application No. 07/891,289, now abandoned.

Page 3, please amend the paragraph beginning at line 7 and ending at line 9:

wherein, the fluid-permeable face mask can demonstrate a negative pressure drop when air is passed into the filtering face mask with a velocity of at least 8 m/s under a normal exhalation test.

Page 7, please amend the paragraph beginning at line 27 and ending at line 36:

As shown in FIGs. 3 and 4, valve seat **26** has a seal ridge **30** that has a seal surface **31** to which the flexible flap **24** makes contact when a fluid is not passing through the valve **14**. An orifice **32** is located radially inward to seal ridge **30** and is circumscribed thereby. Orifice **32** can have cross-members **34** that stabilize seal ridge **30** and ultimately valve **14**. The cross-members **34** also can prevent flexible flap **24** from inverting into orifice **32** under reverse air flow, for example, during inhalation. When viewed from a side elevation, the surface of the cross-members **34** is slightly recessed beneath (but may be aligned with) seal surface 31 to ensure that the cross members do not lift the flexible flap **24** off seal surface 31 (see FIG. 3).

Page 10, please amend the paragraph beginning at line 3 and ending at line 12:

Valve seat **26** preferably is made from a relatively light-weight plastic that is molded into an integral one-piece body. The valve seat can be made by injection molding techniques. The surface **31** of the seal ridge **30** that makes contact with the flexible flap **24** (the contact or seal surface) is preferably fashioned to be substantially uniformly smooth to ensure that a good seal occurs. The contact surface preferably has a width great enough to form a seal with the flexible flap **24** but is not so wide as to allow adhesive forces caused by condensed moisture to significantly make the flexible flap **24** more difficult to open. The width of the contact surface, preferably, is at least 0.2 mm, and preferably is in the range of about 0.25 mm to 0.5 mm.

Page 14, please amend the paragraph beginning at line 33 and ending on page 15 at line 25:

Exhalation valve **14** can be provided with a valve cover to protect the flexible flap **24**, and to help prevent the passage of contaminants through the exhalation valve. In FIG. 7, a valve cover **50** is shown which can be secured to exhalation valve **14** by a friction fit to wall **44**. Valve cover **50** also can be secured to the exhalation valve **14** by ultrasonic welding, an adhesive, or other suitable means. Valve cover **50** has an opening **52** for the passage of a fluid. Opening **52** preferably is at least the size of orifice **32**, and preferably is larger than orifice **32**. The opening **52** is placed, preferably, on the valve cover **50** directly in the path of fluid flow **36** so that eddy currents are minimized. In this regard,

opening **52** is approximately parallel to the path traced by the free end **38** of flexible flap **24** during its opening and closing. As with the flexible flap **24**, the valve cover opening **52** preferably directs fluid flow downwards so as to prevent the fogging of a wearer's eyewear. All of the exhaled air can be directed downwards by providing the valve cover with fluid-impermeable side walls **54**. Opening **52** can have cross-members **56** to provide structural support and aesthetics to valve cover **50**. A set of ribs **58** can be provided on valve cover **50** for further structural support and aesthetics. Valve cover **50** can have its interior fashioned such that there are female members (not shown) that mate with pins **41** of valve seat **14**. Valve cover **50** also can have a surface (not shown) that holds flexible flap **24** against flap-retaining surface **40**. Valve cover **50** preferably has fluid impermeable ceiling **60** that increases in height in the direction of the flexible flap from the fixed end to the free end. The interior of the ceiling **60** can be provided with a ribbed or coarse pattern or a release surface to prevent the free end of the flexible flap from adhering to the ceiling **60** when moisture is present on the ceiling or the flexible flap. The valve cover design **50** is fully shown in U.S. Design Patent Application 29/000,382. Another valve cover that also may be suitable for use on a face mask of this invention is shown in Design Patent Application 29/000,384. The disclosures of these applications are incorporated here by reference.

Page 20, please amend the paragraph beginning at line 24 and ending at line 33:

The exhalation valve of Example 1 was mounted to a 3M 8810 filtering face mask such that the exhalation valve was positioned on the mask body directly opposite to where a wearer's mouth would be when the mask is worn. The airflow through the nozzle was increased to approximately 80 l/min to provide an airflow velocity of 8.3 meters per second (m/s). At this velocity, zero pressure drop was achieved inside the face mask. An ordinary person will exhale at moderate to heavy work rates at an approximate air velocity of about 5 to 13 m/s depending on the opening area of the mouth. Negative and relatively low pressures can be provided in a face mask of this invention over a large portion of this range of air velocity.

Page 22, please replace Table 2:

Examples	*Volume Flow (liters/minute)*	*Pressure Drop (Pa) Nozzle Area: 18.1 cm²*	*Pressure Drop (Pa) Nozzle Area: 2.26 cm²*	*Pressure Drop (Pa) Nozzle Area: 0.96 cm²*	*% Total Flow Nozzle Area: 18.1 cm²*	*% Total Flow Nozzle Area: 2.26 cm²*	*% Total Flow Nozzle Area: 0.95 cm²*
8	12	9.02	8.92	8.92	1	2	2
9	24	15.09	14.21	11.17	19	24	39
10	48	18.62	14.99	4.31	30	60	87
11	60	20.48	15.09	-1.76	56	68	102
12	72	22.34	14.80	-7.55	61	73	112
13	80	24.01	14.41	-12.94	62	77	119

IN THE CLAIMS:

Please cancel claims 1-32.

Kindly add claims 33-64 to this patent application:

33. A filtering face mask that comprises:

(a) a mask body adapted to fit over the nose and mouth of a person; and

(b) an exhalation valve that is attached to the mask body, which exhalation valve comprises:

(1) a valve seat that comprises an orifice and a seal surface, the orifice allowing exhaled air to pass therethrough and being surrounded by the seal surface; and

(2) a single flexible flap non-centrally and operatively supported relative to the orifice of the valve seat and pressed against the seal surface of the valve seat in a closed state of the exhalation valve, the flexible flap assuming, in its closed state, a curved profile in a cross-sectional view thereof, the curved profile comprising a curve that extends from a first point where a first stationary portion of the flexible flap is secured to the valve seat to a second point where a second free portion of the flexible flap contacts the seal surface, the flexible flap being held in its closed state, at least in part, by virtue of the curved profile thereof;

wherein the second free portion of the flexible flap represents the only free portion of the flap and can flex so as to permit exhaled air to pass through the orifice and to provide an open state of the exhalation valve such that the second free portion of the flexible flap is out of contact with the seal surface at the second point while the first portion of the flexible flap remains stationary at the first point.

34. The filtering face mask of claim 33, wherein the valve seat includes one or more cross members that are disposed within the orifice.

35. The filtering face mask of claim 34, wherein the valve seat further includes a flap retaining surface that is located within an internal chamber defined by a valve cover.

36. The filtering face mask of claim 35, wherein the first stationary portion of the flexible flap is held between a flap retaining surface on the valve seat and a second member that is associated with the valve cover.

37. The filtering face mask of claim 36, wherein the flexible flap is secured to the valve by mechanical clamping.

38. The filtering face mask of claim 36, wherein the flexible flap can assume a curved profile, when in its closed state, that extends in from where the flexible flap contacts the second member of the valve cover to where the second portion of the flexible flap contacts the seal surface of the valve seat.

39. The filtering face mask of claim 36, wherein the flap retaining surface is oriented transversely relative to the orifice.

40. The filtering face mask of claim 39, wherein the flap retaining surface is positioned adjacent one side of the orifice.

41. The filtering face mask of claim 37, wherein the flexible flap would normally exhibit a flat configuration but is curved by virtue of the securement of the flap to the valve seat and the relative positioning and alignment between the seal surface and the flap retaining surface.

42. The filtering face mask of claim 35, wherein the flexible flap would normally exhibit a flat configuration but is curved by virtue of the securement of the flap to the valve seat and the relative positioning and alignment between the seal surface and the flap retaining surface.

43. The filtering face mask of claim 33, wherein the valve seat includes a flange portion that defines a mounting surface for the valve seat, which mounting surface extends 360° around the valve seat at its base and enables the valve seat to be secured to the mask body.

44. The filtering face mask of claim 33, wherein the shape of the orifice does not correspond fully to the shape of the seal surface, and wherein the flexible flap is mounted to the valve seat in cantilever fashion.

45. The filtering face mask of claim 33, wherein the exhalation valve also includes a valve cover, the flexible flap being held in position between the valve seat and the valve cover by mechanical clamping.

46. The filtering face mask of claim 33, wherein the curvature of the flexible flap extends not only from the first and second points but also from a third point that is located at where the flexible flap contacts a location on the seal surface opposite the second point.

47. The filtering face mask of claim 33, wherein the valve seat comprises cross members that are disposed within the orifice to define a plurality of openings through which exhaled air can pass during an exhalation to lift the free portion of the flap from the seal surface.

48. The filtering face mask of claim 47, wherein the valve seat includes cross members that are disposed within the orifice and are recessed beneath the seal surface.

49. The filtering face mask of claim 33, wherein the valve seat includes a flap-retaining surface that is spaced from the orifice at about 1 to 3.5 millimeters.

50. The filtering face mask of claim 33, wherein the valve seat is made from a relatively light-weight plastic that is molded into an integral one-piece body.

51. The filtering face mask of claim 33, wherein the seal surface is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface, and wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface.

52. The filtering face mask of claim 33, wherein the flexible flap has a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hours at 70 °C.

53. The filtering face mask of claim 33, wherein the flexible flap is made from a crosslinked polyisoprene.

54. The filtering face mask of claim 33, wherein the flexible flap has a Shore A hardness of about 30 to 50 and has a generally uniform thickness of about 0.2 to 0.8 millimeters.

55. The filtering face mask of claim 33, wherein the second free portion of the flexible flap has a profile that when viewed from the front corresponds to the general shape of the seal surface and comprises a curve.

56. The filtering face mask of claim 33, wherein the flexible flap is 1.2 to 3 centimeters wide and is about 1 to 4 centimeters long.

57. The filtering face mask of claim 33, wherein the flexible flap has a peripheral edge that includes a stationary segment that represents about 10 to 25 percent of the total circumferential edge of the flexible flap, with the remaining 75 to 90 percent of the peripheral edge being free to be lifted from the seal surface.

58. The filtering face mask of claim 33, wherein the flexible flap is positioned on the valve such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person.

59. The filtering face mask of claim 33, wherein the mask body is cup-shaped and includes a filtering material and a shaping layer for providing structure to the mask.

60. The filtering face mask of claim 59, wherein the shaping layer is located outside of the filtration layer on the mask body.

61. The filtering face mask of claim 60, wherein at least 60 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

62. The filtering face mask of claim 33, wherein at least 73 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

63. The filtering face mask of claim 63, wherein the exhalation valve is positioned on the mask body substantially opposite to a wearer's mouth.

64. The filtering face mask of claim 33, wherein the exhalation valve is positioned on the mask body such that the second free portion of the flexible flap resides beneath the stationary portion when the mask is worn on a person.

IN THE ABSTRACT:

Please delete the Abstract and replace with the following Abstract:

A filtering face mask that comprises a mask body adapted to fit over the nose and mouth of a person; and an exhalation valve that is attached to the mask body. The exhalation valve comprises a valve seat and a flexible flap. The valve seat has an orifice through which fluid can pass and is surrounded by the seal surface. The flexible flap is operatively supported relative to the valve seat and pressed against the seal surface of the valve seat in a closed state of the exhalation valve. The flexible flap assumes in its closed state, a curved profile in a cross-sectional view thereof. The curved profile comprises a curve that extends from a first point where a first portion of the flexible flap contacts the seal surface to a second point where a second portion of the flexible flap contacts the seal surface. The flexible flap is held in its closed state, at least in part, by virtue of the curved profile thereof. The second portion of the flexible flap represents the only free portion of the flap and can flex so as to permit exhaled air to pass through the orifice and to provide an open state of the fluid flow valve such that the second portion of the flexible flap is out of contact with the seal surface at the second point while the first portion of the flexible flap is maintained in contact with the seal surface at the first point.

IN THE DRAWINGS:

Please replace the drawing sheet that contains Figs. 4-7 with the attached drawing sheet.

REMARKS

Claims 1-32 have been canceled, and claims 33-64 have been added to this application, Thus, claims 33-64 are now pending in this case.

The specification also has been amended to make a number of corrections to the text and to provide an identifying number for the "seal surface" 31 in the drawings.

Dated this 18th day of April, 2001.

Respectfully submitted,

Karl G. Hanson
Attorney for Applicants
Registration No. 32,900

Office of Intellectual Property Counsel
3M Innovative Properties Company
3M Center, P.O. Box 33427
St. Paul, Minnesota 55133-3427
Telephone: (651) 736-7776
Facsimile: (651) 736-3833

48317USA3M.032\PTO\Preliminary Amendment

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Changes to Specification

Page 3:

wherein, the fluid-permeable face mask can demonstrate a negative pressure drop when air is passed into the filtering face mask with a velocity of at least [0.8] 8 m/s under a normal exhalation test.

Page 7:

As shown in FIGs. 3 and 4, valve seat **26** has a seal ridge **30** that has a seal surface 31 to which the flexible flap **24** makes contact when a fluid is not passing through the valve **14**. An orifice **32** is located radially inward to seal ridge **30** and is circumscribed thereby. Orifice **32** can have cross-members **34** that stabilize seal ridge **30** and ultimately valve **14**. The cross-members **34** also can prevent flexible flap **24** from inverting into orifice **32** under reverse air flow, for example, during inhalation. When viewed from a side elevation, the surface of the cross-members **34** is slightly recessed beneath (but may be aligned with) seal [ridge **30**] surface 31 to ensure that the cross members do not lift the flexible flap **24** off seal [ridge **30**] surface 31 (see FIG. 3).

Page 10:

Valve seat **26** preferably is made from a relatively light-weight plastic that is molded into an integral one-piece body. The valve seat can be made by injection molding techniques. The surface 31 of the seal ridge **30** that makes contact with the flexible flap **24** (the contact or seal surface) is preferably fashioned to be substantially uniformly smooth to ensure that a good seal occurs. The contact surface preferably has a width great enough to form a seal with the flexible flap **24** but is not so wide as to allow adhesive forces caused by condensed moisture to significantly make the flexible flap **24** more difficult to open. The width of the contact surface, preferably, is at least 0.2 mm, and preferably is in the range of about 0.25 mm to 0.5 mm.

Page 14:

Exhalation valve **14** can be provided with a valve cover to protect the flexible flap **24**, and to help prevent the passage of contaminants through the exhalation valve. In FIG. [6] 7, a valve cover **50** is shown which can be secured to exhalation valve **14** by a friction fit to wall **44**. Valve cover **50** also can be secured to the exhalation valve **14** by ultrasonic welding, an adhesive, or other suitable means. Valve cover **50** has an opening **52** for the passage of a fluid. Opening **52** preferably is at least the size of orifice **32**, and preferably is larger than orifice **32**. The opening **52** is placed, preferably, on the valve cover **50** directly in the path of fluid flow **36** so that eddy currents are minimized. In this regard, opening **52** is approximately parallel to the path traced by the free end **38** of flexible flap **24** during its opening and closing. As with the flexible flap **24**, the valve cover opening **52** preferably directs fluid flow downwards so as to prevent the fogging of a wearer's eyewear. All of the exhaled air can be directed downwards by providing the valve cover with fluid-impermeable side walls **54**. Opening **52** can have cross-members **56** to provide structural support and aesthetics to valve cover **50**. A set of ribs **58** can be provided on valve cover **50** for further structural support and aesthetics. Valve cover **50** can have its interior fashioned such that there are female members (not shown) that mate with pins **41** of valve seat **14**. Valve cover **50** also can have a surface (not shown) that holds flexible flap **24** against flap-retaining surface **40**. Valve cover **50** preferably has fluid impermeable ceiling **60** that increases in height in the direction of the flexible flap from the fixed end to the free end. The interior of the ceiling **60** can be provided with a ribbed or coarse pattern or a release surface to prevent the free end of the flexible flap from adhering to the ceiling **60** when moisture is present on the ceiling or the flexible flap. The valve cover design **50** is fully shown in U.S. Design Patent Application 29/000,382. Another valve cover that also may be suitable for use on a face mask of this invention is shown in Design Patent Application 29/000,384. The disclosures of these applications are incorporated here by reference.

Page 20:

The exhalation valve of Example 1 was mounted to a 3M 8810 filtering face mask such that the exhalation valve was positioned on the mask body directly opposite to where a wearer's mouth would be when the mask is worn. The airflow through the nozzle was increased to approximately 80 l/min to provide an airflow velocity of [0.9] 8.3 meters per second (m/s). At this velocity, zero pressure drop was achieved inside the face mask. An ordinary person will exhale at moderate to heavy work rates at an approximate air velocity of about [0.5 to 1.3] 5 to 13 m/s depending on the opening area of the mouth. Negative and relatively low pressures can be provided in a face mask of this invention over a large portion of this range of air velocity.

Examples	*Volume Flow (liters/minute)*	*Pressure Drop (Pa) Nozzle Area: [1.81 cm] 18.1 cm^2*	*Pressure Drop (Pa) Nozzle Area: 2.26 cm^2*	*Pressure Drop (Pa) Nozzle Area: 0.96 cm^2*	*% Total Flow Nozzle Area: 18.1 cm^2*	*% Total Flow Nozzle Area: 2.26 cm^2*	*% Total Flow Nozzle Area: 0.95 cm^2*
8	12	9.02	8.92	8.92	1	2	2
9	24	15.09	14.21	11.17	19	24	39
10	48	18.62	14.99	4.31	30	60	87
11	60	20.48	15.09	-1.76	56	68	102
12	72	22.34	14.80	-7.55	61	73	112
13	80	24.01	14.41	-12.94	62	77	119

Changes to the Abstract

[An exhalation valve **14** for a filtering face mask **10** has a flexible flap **24** that makes contact with a curved seal ridge **30** of a valve seat **26** when the valve **14** is in the closed position. The curvature of the seal ridge **30** corresponds to a deformation curve exhibited by the flexible flap **24** when secured as a cantilever at one end and exposed at its free portion to a uniform force and/or a force of at least the weight of the free portion of the flexible flap. A seal ridge curvature corresponding to a flexible flap exposed to uniform force allows the flexible flap **24** to exert a generally uniform pressure on the seal ridge to provide a good seal. A seal ridge curvature corresponding to a flexible flap exposed to a force of at least the weight of the flap's free portion allows the flexible flap **24** to be held in an abutting relationship to the seal ridge **30** under any static orientation by a minimum amount of force, thereby providing a face mask **10** with an extraordinary low pressure drop during an exhalation.]

A filtering face mask that comprises a mask body adapted to fit over the nose and mouth of a person; and an exhalation valve that is attached to the mask body. The exhalation valve comprises a valve seat and a flexible flap. The valve seat has an orifice through which fluid can pass and is surrounded by the seal surface. The flexible flap is operatively supported relative to the valve seat and pressed against the seal surface of the valve seat in a closed state of the exhalation valve. The flexible flap assumes in its closed state, a curved profile in a cross-sectional view thereof. The curved profile comprises a curve that extends from a first point where a first portion of the flexible flap contacts the seal surface to a second point where a second portion of the flexible flap contacts the seal surface. The flexible flap is held in its closed state, at least in part, by virtue of the curved profile thereof. The second portion of the flexible flap represents the only free portion of the flap and can flex so as to permit exhaled air to pass through the orifice and to provide an open state of the fluid flow valve such that the second portion of the flexible flap is out of contact with the seal surface at the second point while the first portion of the flexible flap is maintained in contact with the seal surface at the first point.